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ABSTRACTS

RESEARCH PODIUM PRESENTATIONS

PODIUM SESSION I: CANCER OUTCOMES RESEARCH

CN1
STATINS AND COLORECTAL CANCER: IS THERE A LINK?

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OBJECTIVES: Studies evaluating the association between statins and colorectal cancer (CRC) have used various methods to address bias and have reported mixed findings. We sought to assess the association in a large cohort of residents in Emilia-Romagna, Italy, using multiple methods to address different sources of confounding. We also sought to explore potential effect measure modification by sex. **METHODS:** We conducted a retrospective population-based new-user cohort study using the 2003–2010 longitudinal healthcare database of Emilia-Romagna, Italy. This comprehensive database contains information on healthcare services rendered to the population, including hospital, outpatient pharmacy and specialty data. We identified all initiators of statins; initiators of glaucoma medications served as the comparison group to account for confounding by healthy user bias. We followed patients longitudinally to identify CRC cases in hospital discharge data. We used multivariable Cox regression analyses to adjust for confounding by CRC risk factors and we conducted a sensitivity analysis using propensity score matching. **RESULTS:** Among 215,963 statin initiators, we observed 1870 cases of CRC, reflecting a crude incidence rate of 222.2 cases per 100,000 person-years. After multivariable adjustment, initiators of statins had a lower incidence rate of CRC as compared to initiators of glaucoma drugs (hazard ratio, 0.79; 95% CI, 0.69 to 0.90). In sex-stratified analyses we observed a protective effect in men (hazard ratio, 0.77; 95% CI, 0.67 to 0.88) but not in women (hazard ratio 0.96; 95% CI, 0.82 to 1.1). Results were similar in propensity score analyses. **CONCLUSIONS:** After adjusting for observed risk factors, statin initiation versus glaucoma drug initiation was associated with a reduced risk of CRC in men but not in women. While this study is subject to many limitations, it corroborates a previous study that found sex differences in the association between statins and CRC.

CN2
DEVELOPMENT OF A PATIENT-REPORTED OUTCOME INSTRUMENT IN BRAIN METASTASES: THE BRAIN METASTASES SYMPTOM AND IMPACT QUESTIONNIARE (BASIQ)

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OBJECTIVES: Patient-reported outcomes (PRO) instruments currently used for patients with brain metastases (BM) have not been developed with adequate patient input from the appropriate population. The objective of this study was to develop a new PRO in this population. **METHODS:** The BASIQ was developed according to the FDA PRO Guidance. A literature review, seven expert interviews, and 19 in-depth interviews with BM patients were conducted to identify the symptoms and impacts of BM important to this population and generate an initial version of the BASIQ. Twenty face-to-face cognitive interviews (CIs) were conducted to assess the content validity of the BASIQ and to assess the understandability, relevance, wording, and importance of items and, if necessary, revise it. **RESULTS:** The initial 23-item BASIQ included a 7-item event log with a yes/no response (assessing vision, reading, nausea, numbness, needing to stay in bed, falling, fainting), 7-item daily symptom section (assessing severity of headache, memory, balance, physical weakness, dizziness, tiredness, energy) on an 11-point NRS, and a 9-item impact section (assessing speaking certain words, putting ideas into words, staying focused on a topic, walking, understanding words read/heard, following a story in a book/on TV, doing things around the house, bathing, dressing). During the CIs, most of the patients reported that the instrument was easy to understand, of adequate length and format and did not contain any difficult words. Based on the CIs, items were deleted, modified, or included as impacts rather than symptoms. A revised 18-item BASIQ used a 24-hour recall period and an 11-point NRS assessing severity. **CONCLUSIONS:** Robust qualitative methods used to identify the symptoms and impacts of patients with BM led to the development of a much needed PRO measure in BM. Additional qualitative and quantitative research is planned to further support the use of the tool in clinical research.

CN3
MULTI-LEVEL MODELING OF OVERALL MORTALITY FOR MEN DIAGNOSED WITH PROSTATE CANCER IN FLORIDA

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OBJECTIVES: To identify individual and contextual factors contributing to overall prostate cancer mortality in Florida. **METHODS:** Using men diagnosed with prostate cancer between 10/1/2001 and 12/31/2007 in the Florida Cancer Data System, the following patient's information were extracted: demographics, type of health insurance at diagnosis, tumor stage, treatment and all-cause death. Census-tract level socioeconomic status & farm house presence were extracted from Census 2000 and linked to patient data. Comorbidity was computed following Elixhauser Index. Multi-level logistic regression was conducted to identify significant individual and contextual factors to overall mortality among the prostate cancer patients. **RESULTS:** 60,497 patients were identified, among whom 8,125 died. Being older at diagnosis, unmarried, current smoker, uninsured, diagnosed at late stage, undifferentiated or unknown tumor grade and poorly differentiated tumor grade were significantly associated with overall mortality. Interaction between stage and grade showed more detrimental late-stage effect as grade worsened and increasingly disadvantageous grade effect at later stage of diagnosis. Low educational attainment of the census tract where patient lived was significantly related to mortality. After adjusting for age, stage and tumor grade, patients who received other treatment categories, except for those who received combined surgery and radiation therapy, were more likely to die compared to those received surgery only. A large number of major comorbidities such as congestive heart failure, peripheral vascular disorder, paralysis, chronic pulmonary disease, diabetes, renal failure, liver disease, a number of other malignancies, etc. were associated with increased risk of mortality. **CONCLUSIONS:** Multi-level modeling allows examination of factors at various levels in relation to patient overall mortality. Patient's demographics, disease stage, comorbidity and available treatment are associated with overall mortality among prostate cancer patients. Although disease specific mortality was not examined, these findings suggest the importance of careful consideration of multiple patient and disease characteristics in treatment decision making.

CN4
TOTAL HEALTH CARE COSTS FOR COLORECTAL CANCER PATIENTS FOLLOWING METASTATIC DIAGNOSIS

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OBJECTIVES: To evaluate health care costs incurred by CRC patients post metastases. **METHODS:** Adult patients with a CRC diagnosis between January 1, 2005 and May 31, 2010 were identified from the Impact Intelligence Oncology Management (IIOM) registry. Patients with stage 4 CRC at diagnosis or development of metastasis were included. Registry data included original stage and date of diagnosis. Linked health care claims from a large US health insurance database affiliated with OptumInsight were used to identify health care costs and patient characteristics. To account for survival, Lin's regression of total 4-year health care costs was conducted comparing stage and controlling for patient characteristics. Variable follow-up ended at earliest of death, disenrollment from health plan, or study end (11/30/10). **RESULTS:** A total of 598 patients, followed for an average of 653 days after first evidence of metastases, were included. At original study diagnosis, 310 patients were stage 4, 197 were unknown stage, and 91 stage 0-3. Mean unadjusted total cost was $252,200; outpatient hospital visits (excluding radiation, surgery) comprised the bulk of that, at a mean cost of $71,334. Hospitalization costs, with or without surgery (mean, $56,862), accounted for 33% of unadjusted mean total medical cost ($176,135). Outpatient office visits, chemotherapy, and biologics were also costly (mean, $36,217, $31,112, $38,276, respectively). On Lin's regression, mean predicted total 4-year costs were: $361,197 (stage 4), $267,728 (originally stage 3; $p=0.014$ vs stage 4), $319,146 (originally stage 0-2; $p=0.514$), and $351,833 (originally unknown stage; $p=0.757$). Looking at the entire IIOM population ($n=1,298$), patients with metastasis, either at index diagnosis or later, had significantly greater costs than patients whose CRC did not metastasize (difference: $138,326; $p<0.001$). **CONCLUSIONS:** Predicted 4-year costs were highest among patients who initially presented with stage 4 CRC, and lowest among patients who presented with stage 3 and developed metastatic disease.